Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of in vitro diagnostic products, vaccines, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products

18–21 September 2017
UN City, Copenhagen, Denmark

Background Note

Session 5: Procurement updates, Introduction to vaccines prequalification for new applicants, WHO/UNFPA prequalification updates by product track, Introduction to WHO pilot prequalification of biosimilars for cancer treatment

Prequalification and post-prequalification vaccines testing

Key information sources / documents

WHO National Control Laboratory Network for Biologicals (WHO-NNB)

WHO-prequalified vaccines are used to immunize approximately two-thirds of infants worldwide. By promoting collaboration in regulatory lot testing according to international standards and best practice, this newly-formed network will help to increase access to quality-assured vaccines in WHO Member States, as well as foster regulatory reliance. Background information about the network and details of the first annual meeting of the network can be found here:

Vaccine-specific standardization

The World Health Organization brings together international experts in specific fields through its biological standardization programme to develop and revise specific recommendations for the production and quality control of vaccines of major international public health importance. Authoritative, harmonized guidelines and recommendations, for use by manufacturers and regulatory authorities, are published in the reports of the Expert Committee on Biological Standards expert coin the WHO Technical Report Series. These include recommendations for individual vaccines, and also more general guidelines on technical or regulatory topics such as cell substrates, nonclinical evaluation, or clinical evaluation. This programme also establishes and distributes the WHO Biological Reference Materials required for the standardization of assays to laboratories around the world such as manufacturers and national control laboratories who are involved in the quality control of vaccines. This activity is critical to ensure the quality of essential vaccines in a global market.

Vaccine-specific standardization information can be found here:
http://www.who.int/biologicals/vaccines/en/

Lot release of vaccines

WHO Member States have requested revised guidelines for lot release of vaccines by NRAs. WHO has therefore initiated a process to develop state-of-the-art guidance for this process. Challenges to the present lot release system include the increased number of vaccines now licensed and in use, the increasing
complexity of new vaccines requiring more sophisticated tests, and the increasing globalization of the industry. These factors create an increasing burden for NRAs and for the industry, particularly for developing countries with limited regulatory experience and resources and often unable to cope with traditional vaccines let alone new biotechnology products.

WHO regulatory guidance on lot release of vaccines can be found here: http://www.who.int/biologicals/areas/vaccines/lot_release_of_vaccines/en/